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*Pro hac vice Application Pending*

Attorneys for Plaintiff Southern Agricultural  
Insecticides, Inc.

UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

**SOUTHERN AGRICULTURAL  
INSECTICIDES, INC.,**

**No. \_\_\_\_\_**

Plaintiff,

**COMPLAINT FOR DECLARATORY  
AND INJUNCTIVE RELIEF**

v.

**ALEXIS TAYLOR**, Director, Oregon  
Department of Agriculture, **TOBY PRIMBS**,  
Pesticide Program Manager, Oregon Department  
of Agriculture, **MICHAEL BABBITT**,  
Pesticide Enforcement, Oregon Department of  
Agriculture,

Defendants.

Plaintiff Southern Agricultural Insecticides, Inc. (“Southern Ag”) respectfully files this Complaint for Declaratory and Injunctive Relief. Defendants are employees of the Oregon Department of Agriculture (“ODA”). Defendants are named in their official capacities.

### **I. NATURE OF THE ACTION**

1. This Complaint arises out of the ODA’s issuance of a Stop Sale Use and Removal Order (“SSURO”) concerning Southern Ag’s insecticide product, Triple Action Neem Oil, EPA Reg. No. 70051-2-829 (“TANO”) on February 14, 2019. ODA amended its initial SSURO directed to Southern Ag twice, once on July 9, 2019, and again on February 3, 2020. In addition, on February 3, 2020, ODA issued a Notice of Violation and Imposition of Civil Penalty and Proposed/Final Order (“NOV”) based on the same pesticide investigation that is the subject of the SSURO. The basis of ODA’s SSURO and NOV is that TANO is adulterated and misbranded under ORS 634.036(15) and 634.036(16).

2. Through the imposition of the SSURO and the NOV, ODA has blocked SAI from selling and distributing throughout the state of Oregon, or elsewhere in the United States, stocks of a lawful product regulated by federal law under the Federal Insecticide Fungicide and Rodenticide Act (“FIFRA”). ODA’s effort to block the distribution and sale of TANO on the basis of its claims is preempted by federal law.

3. The basis of ODA’s SSURO and NOV is its detection of the following insecticidal compounds at the following concentrations in a sample of TANO it tested, the presence of which was not disclosed on the TANO label: malathion (0.15 ppm); chlorpyrifos (0.040 ppm), permethrin (0.24 ppm) (collectively, the “Trace Contaminants”). ODA’s contention that

undisclosed Trace Contaminants it detected in TANO are pesticide active ingredients that must be disclosed on the federally-approved product label is incorrect as a matter of law.

4. Southern Ag seeks a declaratory order that ODA is preempted from enforcing its SSURO and NOV. FIFRA and the regulatory scheme created consistent with it prevent ODA from declaring Southern Ag's TANO as being misbranded and adulterated based on the presence of the Trace Contaminants when the product fully complies with federal labeling requirements, and when the Trace Contaminants are within the permissible level of cross contamination that the U.S. Environmental Protection Agency ("EPA") long ago determined is not required to be disclosed on pesticide labels. Southern Ag thus seeks a declaration that ODA's SSURO and NOV have been unlawfully issued, and seeks an injunction preventing ODA from enforcement of them.

## II. PARTIES

5. Southern Ag is a corporation organized under the laws of the State of Florida. Its principal place of business is Rubonia, Florida.

6. Defendant Alexis Taylor is the Director of the Oregon Department of Agriculture. Defendant Taylor is sued in her official capacity under the rule of *Ex Parte Young*. See *Ex Parte Young*, 209 U.S. 123, 152-154 (1908).

7. Defendant Toby Primbs is the Pesticide Program Manager of the Oregon Department of Agriculture. Defendant Primbs is sued in his official capacity under the rule of *Ex Parte Young*.

8. Defendant Michael Babbitt is a Pesticide Enforcement Officer for the Oregon Department of Agriculture. Defendant Babbitt is sued in his official capacity under the rule of *Ex Parte Young*.

### **III. JURISDICTION AND VENUE**

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and laws of the United States.

10. In addition, this Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Defendants’ actions are preempted by FIFRA §§ 16(c) and 24(b), 7 U.S.C. §§ 136n(c) and § 136v(b), which prohibit Defendants from imposing or continuing in effect “any requirements for labeling or packaging in addition to or different from those required under [FIFRA].”

11. This Court also has jurisdiction over this action under 28 U.S.C. § 1331 and the Supremacy Clause of the U.S. Constitution because Defendants’ actions conflict with federal law.

12. Venue resides in this district pursuant to 28 U.S.C. § 1391(b) because Defendants maintain offices and/or reside within the district. Further, a substantial part of the events giving rise to Southern Ag’s claims occurred in this district and the property that is the subject of the action is situated in this district.

### **IV. FACTUAL ALLEGATIONS**

#### **A. EPA’s Regulation of Pesticides**

##### **i. EPA Comprehensively Regulates Pesticide Labels Under FIFRA**

13. FIFRA is a “comprehensive regulatory statute” governing the distribution, sale and use of pesticides in the United States. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 987, 991 (1984). As defined by FIFRA, a “pesticide” is “any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest.” FIFRA § 2(u)(1), 7 U.S.C. § 136(u)(1). All pesticides sold or distributed in the United States must first be registered with EPA. FIFRA § 3(a), 7 U.S.C. § 136(c).

14. EPA's authority under FIFRA also includes strict regulation of the labeling of pesticide products, including their content. FIFRA § 3(c)(1)(C),(F), 7 U.S.C. §§ 136a(c)(1)(C),(F); *see* 40 C.F.R. § 156.10.

15. To obtain a registration, an applicant must provide EPA, *inter alia*, "a complete copy of the labeling of the pesticide," "the complete formula for the product" called the Confidential Statement of Formula ("CSF"), and prescribed health, safety and environmental data concerning the pesticide to be registered. FIFRA § 3(c)(1)(C),(D), (F); FIFRA § 3(c)(2)(A).

16. EPA will not register a pesticide unless it "has determined that the product is not misbranded ... and its labeling and packaging comply with the applicable requirements" of FIFRA and EPA's implementing regulations. 40 C.F.R. § 152.112(f).

17. Once EPA has granted a registration for a pesticide, it is unlawful to sell or distribute the product without the EPA-approved label. FIFRA § 12(a)(1)(E). EPA-approved labels also must include the statement that "[i]t is a violation of federal law to use this product in a manner inconsistent with its labeling."

18. FIFRA further provides that no State may "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required" under FIFRA. FIFRA § 24(b) ("Authority of States").

## **ii. EPA Requirements for Disclosure of Contaminants in Pesticides**

19. EPA's regulations also define the information that an applicant for a pesticide registration must submit to the Agency regarding the chemical composition of its proposed product. The regulations require the applicant to provide information regarding: (a) each active ingredient, and (b) each inert ingredient, in the product. 40 C.F.R. § 158.320.

20. In addition, the regulations require a pesticide registration applicant to provide information on the “impurities” that may be present in the product, if (1) found in “any chemical analysis of the product” or if (2) “the applicant has reason to believe the impurity may be present at a level of  $\geq 0.1$  percent (1000 ppm) by weight of the technical grade of the active ingredient.” 40 C.F.R. § 158.340. Impurity is defined as “any substance ... in a pesticide product other than an active ingredient or an inert ingredient, including any...contaminants, and degradation products.” *Id.*

21. An applicant must provide an enforcement analytical method for “each active ingredient in the product and for each other ingredient or impurity that the Agency determines to be toxicologically significant.” 40 C.F.R. § 158.355. Likewise, an applicant must disclose to EPA the presence of any contaminant or other impurity not previously disclosed that is in the product in a concentration greater than 1000 ppm or that is otherwise toxicologically significant. 40 C.F.R. §159.179(b).

22. On October 31, 1996, EPA issued Pesticide Regulation (“PR”) Notice 96-8, setting forth EPA’s interpretation of the term “toxicologically significant” in connection with contaminants in pesticide products that could be active ingredients if in sufficient concentration in other products.

23. PR Notice 96-8 generally establishes  $\geq 1000$  ppm (0.1%) as the level that is “toxicologically significant” for insecticide active ingredients (including those that comprise the Trace Contaminants) when present as contaminants in other insecticide products. PR Notice 96-8 has been in force for more than two decades without change.

24. ODA's findings of Trace Contaminants in TANO fall well below EPA's threshold for disclosure of contaminants in pesticide products.

**iii. Southern Ag**

25. Southern Ag is a family-owned insecticide business based in Rubonia (mailing address, Palmetto), Florida.

26. Southern Ag markets about two dozen pesticides for which it holds an EPA registration. Southern Ag also markets several insecticides for which it is not the EPA registrant; as to those products, Southern Ag has been granted permission by the registrant to distribute and sell the product under a "supplemental distribution" (also known as "private label" or "subregistration") arrangement. Supplemental distribution arrangements also are regulated by EPA under FIFRA. FIFRA § 3(e); 40 C.F.R. § 152.132.

27. Under such an arrangement, EPA requires that the label for the subregistered or "distributor" (private label) product be identical to the registrant's EPA-approved label for the product, with a few exceptions: *e.g.*, the distributor may use its own brand name for the product; the distributor's name and address may appear on the label; the distributor's EPA company number must be added at the end of the EPA product registration number listed on the label. 40 C.F.R. § 152.132(d). The distributor label may also omit uses on the label for the registrant's registered product (but it may not add uses not on the registrant's product label).

**iv. TANO**

28. TANO (EPA Reg. No. 70051-2-829) is Southern Ag's subregistered or distributor product, based on the product Neem Oil 70% (EPA Reg. No. 70051-2) ("NO"). NO is an EPA-

registered end-use pesticide product that is registered with EPA and produced by Certis, U.S., based in Columbia, MD. Southern Ag is neither the EPA registrant nor the formulator of TANO.

29. Certis formulates NO by blending registered technical-grade neem oil with certain inert ingredients as specified in the CSF on file with EPA for the product. Certis also holds the registration for technical-grade neem oil, Neem Oil TGAI (EPA Reg. No. 70051-7) that is used in the formulation of NO. Certis delivers formulated NO to Southern Ag at its Rubonia, FL facility in bulk containers bearing Certis' EPA-approved label.

30. As authorized by Certis and EPA's supplemental distribution regulations, Southern Ag then repackages NO into smaller containers bearing Southern Ag's private label version of the EPA-approved label for the product. Because Southern Ag is not the registrant, it was not involved in the application process for the registration of NO – or for Certis' EPA-registered Neem Oil TGAI from which NO is formulated – and has no knowledge of the product chemistry testing Certis conducted on either product. Southern Ag only has a copy of Certis' EPA-approved CSF for NO.

31. Certis' NO label includes a range of agricultural crops, turf and ornamental and residential uses. However, Cannabis (marijuana/hemp) is not a registered use of NO that is permitted by Certis' EPA-approved label. Moreover, as required by Southern Ag's contract with Certis, Southern Ag's TANO label is limited to residential uses only.

32. The EPA-approved directions for use on Certis' NO and Southern Ag's TANO labels instruct the user to dilute the product with water before application. For agricultural uses (relevant to NO only; TANO's label only provides for residential uses) the dilution rate is ½ gallon



product/25 gallon water (2%). For residential uses (relevant to both NO and TANO) the dilution rate is 1 ounce product/1 gallon water ( $1/128 = <1\%$ ).

33. In 2010, TANO was certified by a private organization called the Organic Materials Review Institute (“OMRI”) under the National Organic Program. As part of this certification, OMRI added TANO to its list of “OMRI Listed Products” and authorized Southern Ag to include OMRI’s logo on the TANO label, which states “OMRI Listed for Organic Use”. As authorized by EPA, Southern Ag added the OMRI logo to the TANO label thereafter. However, TANO ceased to participate in this voluntary program in July 2019; TANO no longer bears the OMRI logo on label.

**v. ODA’s Listing of TANO on its “Guide List” for Cannabis Growers**

34. In or about 2017, ODA added TANO to its “guide list” of “pesticide products whose labels do not legally prohibit use on cannabis from those that clearly do not allow use.” *See* <https://www.oregon.gov/oda/programs/pesticides/pages/cannabispesticides.aspx>. ODA did not consult with Southern Ag or obtain its consent prior to taking this action.

35. ODA’s unilateral listing of TANO on the ODA Cannabis “guide list” is inconsistent with the product’s EPA-approved labeling. As noted, TANO’s label authorizes only residential uses of the product on crop and plant species that are identified on the label.

36. The use of TANO on Cannabis is not authorized by the EPA-approved label. The use of TANO for commercial purposes is not authorized by the TANO label. The use of TANO on Cannabis for commercial purposes is not authorized by the label. As a result, the use of TANO for any, or all, of these purposes would be unlawful. FIFRA § 12(a)(2)(G); FIFRA § 2(ee).

**vi. ODA's SSURO, NOV and Conditional Authorization**

37. Upon information and belief, ODA has conducted tests on pesticide products it included in its "guide list" for use on Cannabis.

38. In December 2018, ODA tested a sample of TANO and found the Trace Contaminants, which are insecticidal compounds.

39. On February 14, 2019, ODA issued its initial SSURO concerning TANO, which it has amended twice, once on July 9, 2019, and again on February 3, 2020. ODA also issued the NOV on February 3, 2020. ODA issued the NOV as a Final Order on April 14, 2020.

40. In the SSRUO and the NOV, ODA contends that TANO is adulterated and misbranded because the (EPA-approved) label does not disclose the presence of the Trace Contaminants.

41. ODA also contends that TANO was misbranded and adulterated because the label included a logo offered through a voluntary certification program with the private entity, OMRI. However, as noted, TANO no longer participates in this program so the OMRI logo does not appear on, or would be removed from, any distribution of TANO.

42. Southern Ag timely filed requests for a hearing with the State of Oregon's Office of Administrative Hearings to dispute the imposition of the SSURO and the NOV.

43. At all times, Southern Ag has fully complied with SSURO. Southern Ag promptly notified its distributor, Central Garden and Pet, to stop all sales and distribution of TANO in Oregon, to remove existing stocks from store shelves, and to hold them pending further instructions.

44. ODA issued a Conditional Authorization allowing Southern Ag to recall the remaining stocks from Oregon. However, over the objections of Southern Ag, ODA conditioned the authorization on the requirement that Southern Ag destroy the TANO subject to the SSURO. The TANO was in full compliance with federal law and may be lawfully sold throughout the country. Because of this unlawful and unwarranted condition, Southern Ag has not initiated a recall and the product remains with its distributor.

45. Southern Ag filed a motion to withdraw its request for a hearing with Oregon's Office of Administrative Hearing on April 10, 2020 in order to proceed with this action. ODA issued a Final Order in this matter and ordered Southern Ag to pay a civil penalty of \$814.00 on April 14, 2020.

### **COUNT I** **Declaratory Judgment — FIFRA Express Preemption**

46. Southern Ag realleges and incorporates by reference the allegations set forth in paragraphs 1-45, above.

47. Defendants' actions issuing a SSURO, as applied here, is expressly preempted by federal law.

48. Pesticides are defined under federal law as substances "intended for preventing, destroying, repelling or mitigating" any pest. FIFRA § 2(u)(1). The Trace Contaminants detected in TANO are not intended to prevent or destroy any pest.

49. In addition, the Trace Contaminants cannot, as a practical matter, serve any pesticidal function. ODA's test indicates that malathion constitutes 0.000015%, chlopyrifos 0.0000040%, and permethrin 0.000024%, of the product. The directions for use require that

TANO be diluted with water by more than 100-fold, reducing the concentrations of these insecticide components when the product is applied by another two orders of magnitude.

50. EPA has consistently regulated product constituents that are unintentionally/unavoidably present as contaminants (or, more generally, impurities), not as active or inert ingredients, regardless of their chemical composition. For this reason, and consistent with FIFRA, EPA does not require that contaminants that are chemically the same as active ingredients to be listed in the ingredient statement on the pesticide label.

51. ODA's claim that TANO is misbranded and adulterated because the label failed to identify the presence of the Trace Contaminants in the product as additional active ingredients is directly contrary to FIFRA, EPA's implementing regulations and policies, and EPA's specific approval of the registration and label for NO/TANO.

52. ODA's contention thus seeks to impose a labeling requirement that is "in addition to or different from" those required under federal law, and is therefore expressly preempted by FIFRA § 24(b).

53. Southern Ag seeks declaratory and injunctive relief finding that the SSURO ODA applied to its TANO product is expressly preempted by federal law.

## **COUNT II**

### **Declaratory Judgment — FIFRA Implied Preemption**

54. Southern Ag realleges and incorporates by reference the allegations set forth in paragraphs 1-53, above.

55. ODA's contention that TANO is misbranded and adulterated is also preempted under implied preemption doctrines.

56. As a supplemental distributor of TANO under Certis' NO registration, SAI is required by federal law to use the same label for TANO as the EPA-approved label for NO, with a few narrow exceptions not relevant here. 40 C.F.R. § 152.132(d). Accordingly, if Southern Ag revised the TANO label to comply with ODA's requirement that the compounds at issue be listed as additional active ingredients, Southern Ag would be in violation of federal law.

57. It is impossible for Southern Ag to comply with both EPA and ODA labeling requirements for TANO.

58. To the extent ODA seeks through the SSURO to require Certis to take additional extraordinary steps to eliminate cross contamination that PR Notice 96-8 permits would interfere with EPA's careful balancing of regulatory objectives and is preempted under conflict preemption principles.

59. Southern Ag seeks declaratory and injunctive relief finding that the SSURO ODA applied to its TANO product is impliedly preempted by federal law.

### **PRAYER FOR RELIEF**

WHEREFORE, Southern Ag demands judgment against Defendant as follows:

1) a declaration that ODA's SSURO and NOV have been unlawfully issued and are preempted by FIFRA in that Southern Ag's TANO fully complies with federal labeling requirements and contains permissible levels of cross contaminants that EPA long ago determined are not required to be disclosed on pesticide labels;

2) an injunction prohibiting the Defendant from enforcing the SSURO and NOV/Final Order against Southern Ag's distribution and sale of TANO in Oregon;

3) an injunction prohibiting the Defendant from enforcing the SSRUO and NOV/Final Order against Southern Ag's distribution and sale of TANO in states in addition to Oregon where it lawfully may be sold; and

4) such other and further relief as this Court may deem just and proper.

Dated this 8<sup>th</sup> day of June, 2020.

DUNN CARNEY ALLEN HIGGINS & TONGUE LLP

*/s/ Timothy J. Bernasek*

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